UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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ANTHONY LARON,

Plaintiff,

v.

WRIGHT MEDICAL TECHNOLOGY, INC,

Defendant.

Case No. 2:18-cv-01161-MMD-DJA

ORDER

I. SUMMARY

This is a personal injury action involving a hip-replacement implant device. Plaintiff Anthony Laron brings strict liability and negligence claims against Defendant Wright Medical Technology, Inc. (ECF No. 27.) Before the Court is Defendant's motion for summary judgment[1] (ECF No. 58 ("Motion")) and unopposed motion to seal (ECF No. 59) portions of Plaintiff's deposition transcript and the depositions of Plaintiff's treating physicians, Robert J. Tait, M.D., and Rolf R. Drinhaus, M.D., to protect Plaintiff's confidential medical information.[2] As explained below, the Court will grant Defendant's Motion in part, because Defendant is immune from design defect strict liability, but will also deny it in part, as genuine factual disputes exist on material issues relating to causation, the availability of punitive damages, and Plaintiff's failure-to-warn and negligence claims. The Court will also grant the motion to seal and will dismiss Plaintiff's breach of warranty claim with prejudice per the parties' stipulation.

[1]Plaintiff responded (ECF No. 63) and Defendant replied (ECF No. 64).

[2]Defendant filed its exhibits to its Motion as attachments to the declaration of Defendant's counsel Tyson Hafen (ECF No. 58-1) but separated the deposition excerpts containing Plaintiff's personal medical information and filed those exhibits under seal (ECF No. 60). Plaintiff's excerpted deposition is marked Exhibit A, Tait's excerpted deposition is marked Exhibit B, and Drinhaus's excerpted deposition is marked Exhibit F.

II. BACKGROUND

This case arises from injuries Plaintiff alleges he incurred by receiving Defendant's CONSERVE hip implant product. The following facts are not in dispute unless otherwise noted.

A. Initial Surgery and CONSERVE Implant

On March 16, 2006, Plaintiff underwent a right total hip arthroplasty—or hip replacement surgery—performed by Dr. Rolf R. Drinhaus. (Exh. A, ECF No. 60 at 13.) Dr. Drinhaus replaced Plaintiff's right hip with an implant from Defendant's CONSERVE product line. (ECF No. 27 at 2.) The CONSERVE hip implant system Plaintiff received was a metal-on-metal design, meaning that the acetabular cup, femoral head, and femoral stem were all made of metal. (ECF No. 58 at 10; Exh. D, ECF No. 58-1 at 23.) The implant Plaintiff received had a cobalt chromium alloy acetabular cup and femoral head, and a titanium alloy stem. (*Id.*)

Defendant's CONSERVE products come with an Instructions for Use ("IFU") insert. (Exh. C, ECF No. 58-1 at 10-18.) Defendant relies on the IFU to inform physicians about known risks associated with the products, potential complications, suggested precautions, and other general device information. Two specific warnings in the IFU are relevant to this case. The first is a warning about the metal components in the products:

> **Metal Components.** Some of the alloys used to produce orthopedic prostheses may contain some elements that may be carcinogenic in tissue cultures or intact organisms. Questions have been raised in scientific literature as to whether or not these alloys may be carcinogenic to actual prosthetic recipients. Studies conducted to evaluate these questions have not produced convincing evidence of such phenomenon.

(Exh. C, ECF No. 58-1 at 12.) The second is a warning about some patients' metal sensitivity, listed under the "Adverse Effects" subheading:

> Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts.

(*Id.* at 16.)

Although not fully understood by the medical community in the mid-2000s, one risk associated with metal-on-metal implants is that a patient may develop an acute local tissue reaction in which particles from the metal components shed will wear into the tissue. (ECF No. 63-3 at 5; ECF No. 63-2 at 8-9.) When cobalt-chromium alloys are split into wear particles, they can be toxic and readily absorbed into the blood. (ECF No. 63-7 at 6.) In such an instance, the patient's body can develop thick tissue around the metal particles shed from the device's normal wear. (ECF no. 63-3 at 5.) The tissue that forms around the metal ions is discolored and has an abnormal texture and density. (*Id.*) The development of the tissue alone may cause a patient pain. (*Id.*) Another observed problem is development of "pseudotumors," a phenomenon in which the joint space around the metal-on-metal implant swells and fills with joint fluid, putting pressure on the structures around the hip. (*Id.* at 5-6.) The pseudotumor can give the appearance of being a fluid-filled tumor, when in reality it is just an expansion of the joint capsule. (*Id.* at 6.) If a patient develops a sufficiently severe tissue reaction due to metal particles shed from the implant, they may require revision surgery to stop the pain, swelling, and tissue deterioration. (ECF No. 63-2 at 8-20.)

Dr. Drinhaus stopped using metal-on-metal implants in 2010 because of the risk of adverse tissue reactions and the much higher rate of needed revisions. (ECF No. 63-2 at 7-8.) Indeed, the medical community as a whole moved away from using metal-on-metal implants around 2010-2012. (*Id.*; ECF No. 63-3 at 5.) However, Dr. Drinhaus was not aware of the extent of the risk of adverse tissue reactions when he used a metal-on-metal implant for Plaintiff's surgery in 2006. (*Id.* at 12.) Dr. Drinhaus testified at his deposition that knowing the degree of risk of adverse tissue reaction and the attendant heightened revision rate associated with metal-on-metal implants would have impacted his decision to use a metal-on-metal implant for Plaintiff's surgery, and would at the very least have required a more extensive conversation with Plaintiff about that risk. (*Id.*)

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B. Revision Surgery

Ten years after receiving Defendant's implant, Plaintiff sought treatment for pain in his right hip. (ECF No. 63-5.) Dr. Robert J. Tait treated Plaintiff at the Orthopaedic Institute of Henderson on May 3, 2016. (*Id.*) Plaintiff described his pain to Dr. Tait as "constant" and at a level of "10/10," which worsened if Plaintiff squatted, kneeled, bent over, twisted, moved, laid in bed, ran, walked, stood, or gripped anything. (*Id.*) Dr. Tait ordered x-rays of Plaintiff's hip and observed that the acetabular component was dislodged or dislocated. (ECF No. 63-3 at 3.) After reviewing the imaging, Dr. Tait concluded that Plaintiff needed a revision of his acetabular component in his replaced hip. (ECF No. 63-5 at 2.)

Dr. Tait performed Plaintiff's right hip revision surgery in July 2016. (ECF No. 63-3 at 4.) During the surgery, Dr. Tait observed that the acetabular shell was free-floating and the bone around the implant was necrotic. (*Id.*) Dr. Tait presumed the necrotic bone was caused by cobalt chrome ions around the shell and femur components that had shed from wear. (*Id.*) In his deposition, Dr. Tait testified that he does not know "for sure" that the necrotic bone was caused by cobalt chrome ions, but that through his experience performing revision surgeries, he has observed visual difference between tissue reactions cause by titanium versus cobalt chrome ions and this discoloration appeared to be more like cobalt chrome. (*Id.*) However, Dr. Tait also admitted that necrotic bone could have been caused by the back of the cobalt chrome alloy acetabular cup rubbing improperly against bone, rather than through the expected articulation against the other metal components. (*Id.*)

C. This Action

Plaintiff asserts three theories of liability in the first amended complaint, or "FAC": (1) strict liability, (2) negligence, (3) breach of warranty. (ECF No. 27.) Under his strict liability count, Plaintiff asserts two claims: (a) failure to warn and (b) defective design. (*Id.* at 4-7.) Plaintiff argues that Defendant failed to adequately warn Plaintiff's surgeon of the risks CONSERVE device's all-metal design posed, particularly the chance for

resultant elevated levels of cobalt and chromium in the blood. (*Id.* at 4-5), a design defect claim. (*Id.* at 4-5.) Plaintiff also argues that the all-metal device was defectively designed because its utility was outweighed by the risk of harm due to increased cobalt and chromium levels in the body and that a safer design was available and feasible at the time the all-metal device was on the market. (*Id.* 5-6.)

This action was part of MDL No. 2329 before it was transferred to this Court on June 22, 2018. (ECF No. 2.) Defendant filed its Motion seeking summary judgment at the close of discovery on August 9, 2021. (ECF No. 58.) In his response to the Motion, Plaintiff "voluntarily withdraws and consents to the dismissal of "Count III – Breach of Warranty." (ECF No. 63 at 8.) Defendant does not oppose dismissal. (ECF No. 64 at 5.) The Court will therefore dismiss the breach of warranty claim without prejudice, and will consider Defendant's Motion as to Plaintiff's strict liability and negligence claims only.

III. LEGAL STANDARD

"The purpose of summary judgment is to avoid unnecessary trials when there is no dispute as to the facts before the court." *Nw. Motorcycle Ass'n v. U.S. Dep't of Agric.*, 18 F.3d 1468, 1471 (9th Cir. 1994) (citation omitted). Summary judgment is appropriate when the pleadings, the discovery and disclosure materials on file, and any affidavits "show there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). An issue is "genuine" if there is a sufficient evidentiary basis on which a reasonable fact-finder could find for the nonmoving party and a dispute is "material" if it could affect the outcome of the suit under the governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). Where reasonable minds could differ on the material facts at issue, however, summary judgment is not appropriate. *See id.* at 250-51. "The amount of evidence necessary to raise a genuine issue of material fact is enough 'to require a jury or judge to resolve the parties' differing versions of the truth at trial.'" *Aydin Corp. v. Loral Corp.*, 718 F.2d 897, 902 (9th Cir. 1983) (quoting *First Nat'l Bank v. Cities Service Co.*, 391 U.S. 253, 288-89 (1968)). In evaluating a summary judgment motion, a court

views all facts and draws all inferences in the light most favorable to the nonmoving party. *See Kaiser Cement Corp. v. Fishbach & Moore, Inc.*, 793 F.2d 1100, 1103 (9th Cir. 1986) (citation omitted).

The moving party bears the burden of showing that there are no genuine issues of material fact. *See Zoslaw v. MCA Distrib. Corp.*, 693 F.2d 870, 883 (9th Cir. 1982). Once the moving party satisfies Rule 56's requirements, the burden shifts to the party resisting the motion to "set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 256. The nonmoving party "may not rely on denials in the pleadings but must produce specific evidence, through affidavits or admissible discovery material, to show that the dispute exists," *Bhan v. NME Hosps., Inc.*, 929 F.2d 1404, 1409 (9th Cir. 1991), and "must do more than simply show that there is some metaphysical doubt as to the material facts." *Orr v. Bank of Am.*, 285 F.3d 764, 783 (9th Cir. 2002) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient[.]" *Anderson*, 477 U.S. at 252.

IV. DISCUSSION

The Court first addresses Defendant's unopposed motion to seal certain deposition excerpts, which the Court grants to protect Plaintiff's personal medical information. The Court then addresses Defendant's motion for summary judgment. Because California law exempts medical device manufacturers from strict liability for design defects, the Court will grant Defendant's Motion in part. However, as further explained below, because Defendant has failed to demonstrate that it is entitled to summary judgment on medical causation, Plaintiff's failure-to-warn theory of strict liability, or the availability of punitive damages, the Court also denies the Motion in part.

A. Motion to Seal

As a preliminary matter, the Court agrees that Plaintiff's personal medical information warrants sealing the indicated deposition excerpts. This Court, and others within the Ninth Circuit, have recognized that the need to protect medical privacy

qualifies as a "compelling reason" for sealing records, since medical records contain sensitive and private information about a person's health. *See, e.g.*, *Spahr v. Med. Dir. Ely State Prison*, No. 3:19-CV-0267-MMD-CLB, 2020 WL 137459, at *2 (D. Nev. Jan. 10, 2020); *Sapp v. Ada Cnty. Med. Dep't*, No. 1:15-CV-00594-BLW, 2018 WL 3613978, at *6 (D. Idaho July 27, 2018); *Karpenski v. Am. Gen. Life Cos.*, LLC, No. 2:12-CV-01569RSM, 2013 WL 5588312, at *1 (W.D. Wash. Oct. 9, 2013). Accordingly, the Court will grant the unopposed motion to seal.[3]

B. Summary Judgment

Defendant's Motion focuses on three main arguments. First, Defendant asserts it is entitled to summary judgment on all Plaintiff's claims because Plaintiff has failed to establish medical causation. Second, Defendant argues it is entitled to judgment as a matter of law on Plaintiff's two strict liability claims. Finally, Defendant claims Plaintiff is not entitled to punitive damages as a matter of law. The Court addresses each argument in turn.

1. Medical Causation

Defendant argues it is entitled to summary judgment on all of Plaintiff's claims because Plaintiff has failed to adequately prove medical causation. (ECF No. 58 at 19.) Specifically, Defendant contends that because this is a medically technical personal injury case, Plaintiff is required to supply an expert witness establishing causation, and that Plaintiff has failed to do so. (*Id.* at 19-21.) Plaintiff counters that the testimony of his treating physicians establishes that his injuries were caused by the device, and the testimony of his expert witness, Bastiaan Cornelissen, Ph.D., establishes that the device was defectively designed. (ECF No. 63 at 8-9.) The Court finds that Plaintiff has established that causation is genuinely in dispute and has provided expert and medical

[3]However, Defendant is advised that per the Court's local rules, each exhibit filed electronically must be attached as a separate file. *See* LR IA 10-3 ("Exhibits filed electronically must comply with LR IC 2-2(a)(3)."); LR IC 2-2(a)(3)(A) ("Exhibits and attachments must not be filed as part of the base document in the electronic filing system. They must be attached as separate files."). Because Defendant separated the sealed exhibits, the Court may grant the motion to seal without implicating the other exhibits. In the future, Defendant must file its exhibits as separate attachments.

testimony to that effect, making summary judgment inappropriate. Because resolving genuinely disputed causation is best left to the fact-finder, the Court will deny the Motion.

"To prevail in a negligence action, a plaintiff must show that the defendant owed a legal duty, the defendant breached that duty and the breach proximately caused injury to the plaintiff." *Garcia v. W&W Comm. Development*, 186 Cal.App.4th 1038, 1044 (Ct. App. 2010).[4] "For a strict products liability claim, plaintiff must show 'that the injury to the plaintiff was caused by the defective condition.'" *Monroe v. Zimmer U.S., Inc.*, 766 F.Supp.2d 1012, 1028 (E.D. Cal. 2011) (quoting *Gonzalez v. Autoliv ASP, Inc.*, 154 Cal.App.4th 780, 793 (Ct. App. 2007)). "Once a defendant properly raises the issue of causation on a motion for summary judgment . . . the burden shifts to the plaintiff to demonstrate a genuine issue of material fact as to causation." *Id.*

When "the complexity of the causation issue is beyond common experience, expert testimony is required to establish causation." *Stephen v. Ford Motor Co.*, 134 Cal.App.4th 1363, 1373 (Ct. App. 2005). Expert testimony is required in more complex cases to ascertain whether causation is probable, rather than merely possible. *See Jones v. Ortho Pharm. Corp.*, 163 Cal.App.3d 396, 402-403 (Ct. App. 1985) ("A possible cause only becomes 'probable' when, in the absence of other reasonable causal explanations, it becomes more likely than not that the injury was the result of its action.").

Plaintiff has established a prima facie causation case for his claims. As he points out, there is no real dispute that Plaintiff received the CONSERVE hip implant, that Plaintiff suffered an injury, that those injuries were attributable to the device—from its dislodgment and the adverse tissue reaction. (ECF No. 63 at 8.) There is no suggestion that Plaintiff's injuries came from, or even could have arisen from, another source. *Cf. Jones*, 163 Cal.App.3d at 403-04 (justifying the need for expert testimony because it is

[4]The parties agree that, applying Nevada's choice of law principles, California law applies to all of Plaintiff's claims. (ECF Nos. 58 at 16-19, 63 at 8.) The Court agrees.

"frequently difficult to determine the nature and cause" of cancer, "one of the leading causes of death in the United States"). Here, the main disputed question is not whether Defendant's device caused Plaintiff's pain, development of necrotic bone, and adverse tissue reactions, but whether the device was defective as designed and whether Defendant's warning was adequate. Plaintiff provides expert testimony on these questions via Cornelissen.[5] In his deposition, Cornelissen explained that the device's materials "are known toxic [sic] to a human body" and explains that the function of the device would necessitate high rates of wear without any lubricant, and states that he "can't understand how that was considered an acceptable design approach." (ECF No. 63-7 at 5.) The Court finds that Cornelissen's testimony is sufficient to create a dispute as to whether Defendant's device was defectively designed.

Defendant does not challenge Drs. Drinhaus or Tait as to their competency or authority to explain to the jury the probable causes of Plaintiff's injuries. Instead, Defendant argues that neither expert have conclusively established that Plaintiff's injuries were attributable to the allegedly defective design of the implant. (ECF No. 58 at 22.) Defendant is correct that a jury could find that Plaintiff's injuries were caused by a properly designed implant which, over time, became dislodged due to no fault of Defendant. But it is not Plaintiff's burden at this time to conclusively prove that (1) Defendant's product was defectively designed and (2) the defective design caused his injuries. *See Monroe*, 766 F.Supp.2d at 1028. Instead, Plaintiff must show that there is a genuine factual dispute of causation. Viewed in the light most favorable to Plaintiff, a reasonable juror could similarly find that the metal-on-metal design was probably, not merely possibly, the cause of Plaintiff's injuries. The Court will therefore deny the Motion as to Defendant's causation arguments, as a genuine dispute of material fact exists and

[5]Defendant suggests that it will move to preclude Cornelissen from opining on medical causation, but has not yet done so. (ECF No. 58 at 21 n.4.) Even if Defendant had so moved, however, it is not apparent that Cornelissen's testimony would not be sufficient to satisfy the requirement that an expert give testimony as to the defective design, nor that Drs. Drinhaus and Tait's testimonies would be insufficient as to medical causation.

Plaintiff has met his burden of providing expert and non-expert testimony which would instruct the jury on the more complex areas of his claims.

2. Strict Liability Claims

California law extends strict liability to three general types of product defect: (1) manufacturing defect, (2) design defect, and (3) failure to warn. *See Brown v. Superior Court*, 751 P.2d 470, 474 (Cal. 1988). "[A] product is defectively designed if it failed to perform as safely as an ordinary consumer would expect when used as intended or reasonably foreseeable, or if, on balance, the risk of danger inherent in the challenged design outweighs the benefits of the design." *Id.* (citing *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 454 (Cal. 1978)). A product may also be "dangerous because it lacks adequate warnings or instructions." *Brown*, 751 P.2d at 475.

The Court will first address Plaintiff's failure-to-warn claim, then will address the design defect claim. Because there is a factual dispute about the adequacy of Defendant's warning, the Court will deny the Motion as to the failure-to-warn claim. However, because the Court finds that California law exempts medical device manufacturers from strict liability for design defects, as further explained below, the Court will grant the Motion as to Plaintiff's strict liability design defect claim.

a. Failure-to-Warn

Defendant argues it is entitled to summary judgment on Plaintiff's failure to warn claim because it discharged its duty to warn through the learned-intermediary doctrine by warning to Dr. Drinhaus via the IFU. (ECF No. 58 at 2.) Alternatively, Defendant argues that even had its warnings been inadequate, Dr. Drinhaus testifies he was independently aware of the potential risk of metal-on-metal implants. (ECF No. 58 at 2.) Plaintiff does not contest that the learned-intermediary theory applies, but rather argues that the warnings were too broad to have adequately informed Dr. Drinhaus of the severity of the risks associated with its device. (ECF No. 63 at 12.) Moreover, Plaintiff argues, Dr. Drinhaus's testimony in totality reflects that he did not have independent

knowledge of the risks, and any argument about his independent knowledge is insufficient. (*Id.*) The Court agrees with Plaintiff as to both arguments.

Because failure-to-warn claims must ultimately prove "not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury," such a claim will not survive summary judgment if "stronger warnings would not have altered the conduct of the prescribing physician." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017) (applying California law and quoting *Motus v. Pfizer Inc.*, 196 F.Supp.2d 984, 991 (C.D. Cal. 2001) and *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004)). "In general, the adequacy of the warning is a question of fact for the jury." *Oxford v. Foster Wheeler LLC*, 177 Cal.App.4th 700, 717 (Cal. Ct. App. 2009).

Defendant has failed to show there is no genuine dispute of material fact as to whether the warnings in the IFU were adequate. Dr. Drinhaus testified that "there was not much known about adverse tissue reactions" when metal-on-metal implants came on the market in America, and that it was not something he was aware of in 2006. (ECF No. 63-2 at 7.) Although he then qualifies that assertion by stating that he thought "it was being brought up at meetings," he was not yet aware of the higher rates of revision for metal-on-metal implants which he now considers "unacceptably" high. (*Id.* at 7-8.) Perhaps most important is Dr. Drinhaus' testimony that had he known then what he now knows about metal-on-metal implants, it would have impacted his decision to use one. (*Id.* at 12.) Viewing the evidence in the light most favorable to Plaintiff, Defendant has not shown that the warning in the IFU adequately informed Dr. Drinhaus of the risks its device posed to his patients or that Dr. Drinhaus would have decided to use its device or any other metal-on-metal implant had the warning been stronger. The Court will therefore deny Defendant's Motion as to Plaintiff's failure-to-warn strict liability claim.

b. Design Defect

Defendant further claims it is immune from strict liability based on a design defect theory under California law. (ECF No. 58 at 27.) This Court, sitting in diversity, is obliged

to apply California law as the California Supreme Court would. *See In re Cnty. of Orange*, 784 F.3d 520, 531 (9th Cir. 2015) (finding that a federal court sitting in diversity adjudicating a state-created right is effectively a court of that state and should endeavor to resolve the claim as would any court of that state). "Where the state's highest court has not squarely addressed an issue, we must 'predict how the highest state court would decide the issue using intermediate appellate court decisions, decisions from other jurisdictions, statutes, treatises, and restatements as guidance.'" *Judd v. Weinstein*, 967 F.3d 952, 955-56 (9th Cir. 2020) (quoting *Lewis v. Tel Emps. Credit Union*, 87 F.3d 1537, 1545 (9th Cir. 1996)). Here, the California Supreme Court has not squarely decided the parameters of immunity from design defect strict liability for manufacturers of medical devices. It falls to this Court to predict how the California Supreme Court would resolve that issue, which involves considering the California Courts of Appeal decisions.

California law does provide an exception from design defect strict liability for manufacturers in certain circumstances involving medical products. *See Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988) (holding manufacturers immune from strict liability for pharmaceutical design defects); *Artiglio v. Superior Court*, 22 Cal.App.4th 1388, 1392 (Ct. App. 1994) (applying the *Brown* exemption to manufacturer of breast implants); *Plenger v. Alza Corp.*, 11 Cal.App.4th 349, (Ct. App. 1992) (applying the *Brown* exemption to manufacturer of IUDs); *Hufft v. Horowitz*, 4 Cal.App.4th 8, 17 (Ct. App. 1992) (applying the *Brown* exemption to manufacturer of penile prostheses).[6] Indeed, California courts have recognized that "the public interest in the development, availability, and affordability of implanted medical devices justifies an exemption from design defect strict products liability for all implanted medical devices." *Garrett v. Howmedica Osteonics Corp.*, 214 Cal.App.4th 183 (Ct. App. 2013) (citing *Hufft*, 4 Cal.App.4th at 19 (Ct. App. 1992)). California Courts view this exemption as "categorical

[6]While the California Supreme Court has not ruled on whether *Brown* extends to medical implants, three of the four California Courts of Appeal have found that it does.

and is not determined on a case-by-case basis." *Id.* (citing *Artiglio*, 22 Cal.App.4th at 1397 (Ct. App. 1994)). As a result, some federal courts have recognized that "*Brown* and its progeny clearly exempt medical device manufacturers from strict liability for design defects." *Hannan v. Boston Sci. Corp.*, Case No. 19-cv-08453-PJH, 2020 WL 2128841, at *5 (N.D. Cal. May 5, 2020); *see also Tucker v. Wright Med. Tech., Inc.*, Case No. 11-cv-03086-YGR, 2013 WL 1149717, at *5 (N.D. Cal. Mar. 19, 2013) (quoting *Artiglio*, 22 Cal.App.4th at 1397, and holding "the determination that strict liability based on design defect is unavailable for all such claims is one to be made as a matter of law").

Plaintiff does not dispute that under *Hufft*, *Plenger*, and *Artiglio*, medical device manufacturers may be immune from strict liability for design defect. (ECF No. 63 at 14.) Plaintiff argues instead that Defendant is not automatically entitled to immunity because its product is a medical device, and reads *Hufft* as imposing certain prerequisites to immunity, specifically requiring that a manufacturer show (1) the device was "properly made" and (2) distributed with information regarding risks and dangers of which the manufacturer knew or should have known at the time." (*Id.*) In *Hufft*, the California Court of Appeal held:

> Following *Brown*'s lead, we draw a bright line within which the comment k test is applied to all implanted medical devices. We hold that a manufacturer is not strictly liable for injuries caused by an implanted prescription medical product which has been (1) properly made and (2) distributed with information regarding risks and dangers of which the manufacturer knew or should have known at the time.

4 Cal.App.4th at 19-20 (citing *Brown*, 751 P.2d at 470).[7] Such language appears to support the conclusion that only where there is not a manufacturing defect or failure-to-

[7]The California Court of Appeal case *Plenger*, which followed *Hufft*, likewise contains this restriction. *See Plenger*, 11 Cal.App.4th at 359-61 (holding the defendant "not strict liable for injuries caused by the [device] if it (1) was properly manufactured and (2) was distributed with adequate information regarding the risks and dangers of which [the manufacturer] knew or should have known at the time."). *But see Artiglio*, 22 Cal.App.4th at 1397 (omitting the restrictive language, holding "[w]e therefore follow the lead of the *Hufft* and *Plenger* courts, and conclude that the entire category of medical implants available only by resort to the services of a physician are immune from design defect strict liability.").

warn defect should a manufacturer automatically be exempted from design defect liability. Here, Plaintiff concedes that the device appears to be manufactured as intended, but further argues that the dispute of whether Defendant's warnings were adequate precludes immunity from design defect strict liability.

The Court disagrees that the California Supreme Court would be persuaded by Plaintiff's analysis. The California Courts of Appeal cases that exempt device manufacturers from design defect strict liability draw from two sources of authority: (1) comment k to § 402A of the Second Restatement of Torts and (2) the California Supreme Court's decision in *Brown v. Superior Court* which, in turn, examined comment k. Applying the California Supreme Court's reasoning in *Brown* to predict its likely application of comment k immunity to medical device manufacturers, the Court agrees with Defendant that it would be immune from design defect strict liability.

Comment k recommends exempting manufacturers of "new or experimental drugs" which "because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety." Restatement (Second) of Torts, § 402A cmt. k (1965). The Restatement justifies the risk of such relatively untested medical innovations because they "cannot legally be sold except to physicians." *Id.* However, the Restatement repeatedly qualifies the recommendation of exemption from liability, explaining "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous." *Id.* (emphasis in original).; *see also id.* ("The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public an apparently useful and desirable product, attended with a known but apparently reasonable risk.").

The *Brown* court expressly examined comment k when it exempted prescription drug manufacturers from design defect strict liability. *See* 751 P.2d at 416-418. That court concluded "(1) a drug manufacturer's liability for a defectively designed drug

should not be measured by the standards of strict liability; (2) because of the public interest in the development, availability, and reasonable price of drugs, the appropriate test for determining responsibility is stated in comment k," and rejected Courts of Appeal holdings finding that comment k's exemption was only available to prescription drugs which were "unavoidably dangerous." *Id.* at 418.

Moreover, the *Brown* court addressed the language Plaintiff points to in comment k regarding the manufacturer's duty to provide reasonable warnings. *Id.* at 417. Because comment k's language "focuses not on a deficiency in the product—the hallmark of strict liability—but on the fault of the producer in failing to warn of dangers inherent in the use of its product that were either known or knowable—an idea which 'rings of negligence.'" *Id.* (quoting *Cronin v. J.B.E. Olson Corp.*, 501 P.2d 1153, 1162 (Cal. 1972)). "Strict liability," the *Brown* court reasoned, "differs from negligence in that it eliminates the necessity for the injured party to prove that the manufacturer of the product which caused the injury was negligent." *Id.* at 415. The court further explained that an open question of strict liability for failure-to-warn does not impact the unavailability of strict liability for design defect, as the language in comment k refers to different grounds for failure-to-warn liability:

> The test stated in comment k is to be distinguished from strict liability for failure to warn. Although both concepts identify failure to warn as the basis of liability, comment k imposes liability only if the manufacturer knew or should have known of the defect at the time the product was sold or distributed. Under strict liability, the reason why the warning was not issued is irrelevant, and the manufacturer is liable even if it neither knew nor could have known of the defect about which the warning was required. Thus, comment k, by focusing on the blameworthiness of the manufacturer, sets forth a test which sounds in negligence . . .

Id. at 417 n.4.

Applying the California Supreme Court's reasoning in *Brown*, this Court can see no clear indication that it would depart from that rationale in this case. Despite that some Courts of Appeal decisions do imply that a proper warning is a prerequisite to immunity, California's highest court rejects that comment k provides a limited immunity from design defect that is predicated on adequate warning. Because this Court is bound

to follow California law and must predict how the California Supreme Court would resolve this issue, irrespective of how this Court would separately interpret comment k, Plaintiff's reasoning is not ultimately persuasive. The Court will therefore grant Defendant's Motion as to Plaintiff's strict liability design defect claim. However, because nothing in *Brown* or its progeny suggest that manufacturers are exempt from a negligence theory of design defect, and in fact suggest the contrary, Plaintiff may proceed with his design defect claim under a negligence theory.

3. Punitive Damages

Defendant also argues that based on the evidence submitted, Plaintiff is not entitled to seek punitive damages. (ECF No. 58 at 34-35.) The Court disagrees.

Defendant's argument is predicated on its warning in the IFU. (*Id.*) Defendant cites to out-of-state and out-of-circuit law for the proposition that even an inadequate warning is sufficient to dispel the state of mind requirement to justify punitive damages. (*Id.*) As Plaintiff rightly points out, a question of fact exists as to the availability of punitive damages. (ECF No. 63 at 15.) California law permits an award of punitive damages when the Plaintiff proves "by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice." Cal. Civ. Code § 3294(a). "Oppression" is defined under California law as "despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person's rights." *Id.* at § 3294(c)(2). Defendant's response that there is no evidence of fraud or misrepresentation is not responsive to Plaintiff's argument that a reasonable juror could find Defendant's conduct was despicable, caused Plaintiff unjust hardship, and that Defendant knew of that risk and consciously disregarded it. As explained above, a question of fact exists as to whether the warnings in the IFU were adequate to inform Dr. Drinhaus of the severity and likelihood of potential complications. Defendant has failed to show that, viewed in the light most favorable to Plaintiff, a jury could not find its conduct was oppressive. The Court will therefore deny Defendant's Motion as to punitive damages.

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V. CONCLUSION

The Court notes that the parties made several arguments and cited to several cases not discussed above. The Court has reviewed these arguments and cases and determines that they do not warrant discussion as they do not affect the outcome of the motions before the Court.

It is therefore ordered that Defendant's motion to seal (ECF No. 59) is granted.

It is further ordered that Defendant's motion for summary judgment (ECF No. 58) is granted in part and denied in part, as explained herein. Plaintiff's strict liability design defect and breach of warranty claims are dismissed, and Plaintiff's strict liability failure-to-warn, negligent failure-to-warn, and negligent design defect claims may proceed.

DATED THIS 28th Day of February 2022.

MIRANDA M. DU
CHIEF UNITED STATES DISTRICT JUDGE